K121757

HealthmateForever ® Healthmate International, LLC

709 E 97th St. , Kansas City MO 64131 Tel: 816 248 1318

Section 5 510(k) Summary

NOV 20 2012

1. Submitter's Identifications

Submission type: abbreviated
Basis for submission: New device
Submitter's Name: Healthmate International, LLC
Address: 709 East 97th Street, Kansas City MO 64131
Contact Person: Mei Dodson
Contact Email: maykc816@yahoo.com
Tel: 816 248 1318
Prepared date: 9/28/2012

2. Correspondent's Identifications

Correspondent's Name: Healthmate International, LLC
Address: 709 East 97th Street, Kansas City MO 64131
Contact Person: Mei Dodson
Contact Email: maykc816@yahoo.com
Tel: 816 248 1318

3. Name of the Device

Device Classification Name: Stimulator, Muscle, Powered, Over-the-Counter
Device Name: TENS and Powered Muscle Stimulator
Models: Pro-8AB, Pro-8IS, Plus-6AB, Plus-6IS, TCM-6L, iTone
Trade Name: HealthmateForever ®
Regulation Number: 21 CFR 882.5890 OTC & 21 CFR 882.5850.
Product Code: NUH & NGX
Device Classification: Class II

4. The Predicate Device

K102598	JQ-5C	TENS	21 CFR 882.5890 OTC
K102598	JQ-5C	PMS	21 CFR 882.5850 OTC

5. Device Description

Pro-8AB is portable; battery powered (3.7V DC) multi-function device offering both Transcutaneous Electrical Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS) qualities in one device.

Double or single channel that effectively transfer your desired choice of programmed electrical pulses directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, causing minimal muscle contractions. There are 6 modes or 8 modes of operations.
The electrodes that we choose to use with the devices, and that any technical characteristics that are

dependent on the chosen electrodes are consistent with the electrodes that we choose to use with the devices.

6. Intended Use of Device

TENS:

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

PMS:

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

The intended use is the same as the predicate device.

7. Summary of Substantial Equivalence

Table: The difference between a series of new devices and Predicate JQ-5C.

Quantity	Pro-8AB, Pro-8IS, Plus-6AB, Plus-6IS, TCM-6L, iTone	JQ-5C
Max Voltage over 10kΩ, V	100	84
Max. Current over 10kΩ, mA	10	8.4
Max. Voltage over 2.2KΩ, V	90	79.2
Max. Current over 2.2KΩ, mA	45	39.6
Max. Voltage over 500,V	70	62.4
Max. Current over 500, mA	140	124.8
Pulse Width, μseconds	90	100
Pulse period, msec	10-836	16.3-781
Max. Pulse Frequency, Hz	100	61.3
Max Charge per Phase over 500Ω, μC	15.66	17.92
Max Current Density over 500Ω, mA/cm2	M1: 6.48@500Ω M2: 5.6@500Ω M3: 7.2@500Ω M4: 5.6@500Ω M5: 5.6@500Ω M6: 7.2@500Ω 5.6@500Ω 6.48@500Ω M7: 5.76@500Ω M8: 6.48@500Ω 5.6@500Ω 7.2@500Ω	9.92

	5.6@500Ω 5.6@500Ω	
Max. Average Power Density over 500Ω, mW cm2	M1: 0.52@500Ω M2: 0.39@500Ω M3: 0.65@500Ω M4: 0.39@500Ω M5: 0.39@500Ω M6: 0.65@500Ω 0.39@500Ω 0.52@500Ω M7: 0.41@500Ω M8: 0.52@500Ω 0.39@500Ω 0.65@500Ω 0.39@500Ω 0.39@500Ω	2.72
Max Current Density over 500Ω, mA/cm2	M1: 3.6@500Ω M2: 3.1@500Ω M3: 4@500Ω M4: 3.1@500Ω M5: 3.1@500Ω M6: 4@500Ω 3.1@500Ω 3.6@500Ω M7: 3.2@500Ω M8: 3.6@500Ω 3.1@500Ω 4@500Ω 3.1@500Ω 3.1@500Ω	9.92
Max. Average Power Density over 500Ω,mW cm2	M1: 0.29@500Ω M2: 0.22@500Ω M3: 0.36@500Ω M4: 0.22@500Ω M5: 0.22@500Ω M6: 0.36@500Ω 0.22@500Ω 0.29@500Ω M7: 0.23@500Ω M8: 0.29@500Ω 0.22@500Ω 0.36@500Ω 0.22@500Ω 0.22@500Ω	2.72

8. Substantial Equivalence

The electrical stimulation provided by a series of model Pro-8AB, Pro-8IS, Plus-6AB, Plus-6IS, TCM-6L and iTone are substantially equivalent to that commonly employed by muscle stimulators and TENS devices that have been cleared for marketing without prescription labeling: i.e., for OTC sale. The pulses in the wave form combinations are restricted in amplitude and duration to values consistent with the other device quoted above.

Technological characteristics, features, specifications, materials and intended uses of the series of model Pro-8AB, Pro-8IS, Plus-6AB, Plus-6IS, TCM-6L and iTone are substantially equivalent to the quoted predicate device.

The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Model Pro-8AB, Pro-8IS, Plus-6AB, Plus-6IS, TCM-6L and iTone modes that offer substantially equivalent technical specifications, features and effective results as the predicate listed.

9. Non-Clinical Tests Performed

Compliance to applicable voluntary standards include: IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO 10993-5 and ISO 10993-10.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

10. Conclusion:

The electrical stimulation provided by a series of model Pro-8AB, Pro-8IS, Plus-6AB, Plus-6IS, TCM-6L and iTone are similar to the commonly employed muscle stimulators and TENS devices that have been cleared for marketing without prescription labeling.

These models have the same intended use and the similar technological characteristics as this OTC predicate. Moreover, verification and validation tests contained in this submission demonstrate that the differences in these models still maintain the same safety and effectiveness as that of the cleared device.

In other words, those engineering differences do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

Concerns of safe and proper use of electrodes and electrode pad placement have been fully addressed by making the use conscious of the proper placement of the electrodes and proper operations of the device through detail in the User's Instruction Manual.

We believe that there are no new safety or effectiveness issues concerning this device to be introduced.

The safety of the device, to be used for the proposed indications without medical prescriptions or supervision, is established by the fact that no adverse events have been reported since 2007 with over 100,000 units sold without a prescription in Europe and Asia.

Over 100,000 units sold with no adverse effects reported, proves its specific technical, safety measures and features are safe and effective when used without medical supervision.

The effectiveness of the device for the proposed indications is supported by a number of customer re

views, which demonstrate that electrical stimulation does improve muscle performance as well as temporary pain reduction.

Technological characteristics, features, specifications, materials and intended uses of the series of model Pro-8AB, Pro-8IS, Plus-6AB, Plus-6IS, TCM-6L and iTone are substantially equivalent to the quoted predicate device.

The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Model Pro-8AB, Pro-8IS, Plus-6AB, Plus-6IS, TCM-6L and iTone offer substantially equivalent technical specifications, features and effective results as the predicate listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 21, 2012

Healthmate International, LLC
% Ms. Mei Dodson
709 E. 97th Street
Kansas City, Missouri 64131

Re: K121757
Trade/Device Name: HealthmateForever Pro-8AB; Pro-8IS; Plus-6AB; Plus-6IS; TCM-6L; and iTone Models
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: November 9, 2012
Received: November 14, 2012

Dear Ms. Dodson:

This letter corrects our substantially equivalent letter of November 20, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

HealthmateForever ® Healthmate International, LLC

709 E 97th St., Kansas City MO 64131 Tel: 816 248 1318

Section 4 Indications for Use

510 (k) Number (if known): K121757
Device Name: TENS & PMS
Models: Pro-8AB, Pro-8IS, Plus-6AB, Plus-6IS, TCM-6L & iTone
Indications for use:

TENS (Transcutaneous Electrical Nerve Stimulation)
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

PMS (Powered Muscle Stimulator)
It is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

Prescription Use_____ AND/OR Over-the-Counter Use ___x___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANTOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Neurological and Physical Medicine Devices
510(k) Number K121757